



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-day Comment Request; Web-Based Resource for Youth About Clinical Research

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on 3/12/2015 pages 13013-13014, and allowed 60-days for public comment. One public comment was received. The purpose of this notice is to allow an additional 30 days for public comment. The National Heart, Lung and Blood Institute (NHLBI), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: NIH Desk Officer.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Ms. Victoria Pemberton, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Dr., Room 8102, MSC 7940, Bethesda, MD 20892-7940, or call non-toll-free number 301-435-0510, or E-mail your request, including your address to pembertonv@nhlbi.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Web-based Resource for Youth about Clinical Research (NHLBI), 0925-New, National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose and use of the information collection for this project is to develop a comprehensive web-based resource for youth with chronic illnesses or diseases that will attempt to increase knowledge, self-efficacy, and positive attitudes towards participation in various clinical trials and research. As a result of the proposed web-based resource, the knowledge gained from developing and testing this web-based resource will ultimately help equip youth to make informed decisions about clinical research and increase motivation to participate in that research. In

addition, the knowledge gained will be invaluable to the field of clinical research given the need for more clinical trials with youth. Specifically, the proposed web-based resource will be an interactive, multimedia, developmentally appropriate resource for youth to be educated about pediatric clinical trials. The resource will be developed for youth aged 8 to 14 years. The theme of “investigative cyber-reporting” will be used throughout and will include youth making a series of decisions about different aspects of participating in clinical research studies. Youth will be tasked with the responsibility of learning all they can about clinical research trials in order to facilitate their knowledge and decision-making processes. Language typically used in journalism and design elements reminiscent of journalism will be incorporated into the content, design, and layout of the resource. There are three main components that will comprise the web-based resource. These include an interactive learning module, full length video testimonials, and an electronic comic book. The benefits and necessities for this particular research on pediatric clinical trials are congruent with NHLBI’s research goals and mission statement: attempting to assist in the enhancement of the health of individuals so that they can live longer and more fulfilling lives. The current lack of knowledge surrounding pediatric clinical trials can be dangerous and unhealthy towards the lives of youth, becoming a large public health need.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 172

Estimates of Hour Burden

| Form Name | Type of Respondents | Number of Respondents | Number of Responses per Respondent | Average Burden Per Response (in hours) | Total Annual Burden Hour |
|--|----------------------------|------------------------------|---|---|---------------------------------|
| Individual Interview Parent Permission Form | parents | 9 | 1 | 5/60 | 1 |
| One-to-One Evaluation Study Parent Permission Form | parents | 5 | 1 | 5/60 | 0.42 |
| Pre-Post Feedback Study Parent Permission | parents | 34 | 1 | 5/60 | 3 |
| Individual Interview Child Assent Form | youth | 9 | 1 | 5/60 | 1 |
| One-to-One Evaluation Study Child Assent Form | youth | 5 | 1 | 5/60 | 0.42 |
| Pre-Post Feedback Study Child Assent Form | youth | 34 | 1 | 5/60 | 3 |
| Individual Interview Questions (Feature Stories) | youth | 3 | 1 | 2 | 6 |
| Individual Interview Questions (Family Spotlights) | youth | 3 | 1 | 2 | 6 |
| Individual Interview Questions (Comic Book) | youth | 3 | 1 | 2 | 6 |
| One-to-One Evaluation Study Questionnaire | youth | 5 | 1 | 2 | 10 |
| Pre-Post Feedback Study Questionnaire | youth | 34 | 1 | 4 | 136 |

Dated: July 30, 2015.

Valery Gheen,

NHLBI Project Clearance Liaison,

National Institutes of Health.

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